

Your Premier Partner for LNP Development

JenKem Technology Co., Ltd (Stock Code: 688356.SH) is specialized in large scale GMP manufacture of high quality LNP excipients, with an outstanding performance in impurity content, batch-to-batch consistency, analytical capability, and customization varieties. We provide both lab-scale and GMP kilo-scale excipients for LNP delivery systems, applicable for the delivery and modification of all types of oligonucleotide therapeutics.

With specialized teams in custom synthesis, analytical method development, and quality research dedicated to LNP excipients, JenKem can offer end-to-end services throughout the R&D and commercialization of oligonucleotide drug pipelines, from excipient synthesis and screening to GMP manufacturing and drug excipient registration. We fully accommodate diverse client needs across R&D, clinical, and commercial phases, while helping mitigate IP risks and driving projects forward efficiently forward efficiently.

JenKem Technology's Capabilities

- Annual Capacity 12-20mt, Batch Size up to 100kg
- Supporting 11 Commercial Drugs (Including 1 vaccine) and 16 Commercial Medical Devices Worldwide
- 165 Active Patents
- Over 600 Catalogue Products
- 19 FDA DMFs, 7 Registration in CDE, 1 Registration in HSA
- Following ICHQ7 Guidelines for GMP Manufacture
- ISO 9001, ISO 13485, ISO 45001, ISO 14001, ISO 50001, ISO 27001, ISO 20400 Certified



Tianjin Facility: Annual Capacity of 2MT with Batch Size up to 10kg



Liaoning Facility: Annual Capacity of 12-20 MT with Batch Size up to 100 kg

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LNP Excipients

- GMP Manufacture
- Custom Synthesis and Encapsulation
- IND-Related Services
- Quality Studies

LNP-Related Analytical Testing Services

JenKem’s analytical method development platform provides analytical services for bio-pharmaceutical products such as LNP-mRNA or siRNA, for efficient analytical support at the initial stage of compound screening and optimization.

Our mRNA analytical method development platform aids with the characterization of the capping and tailing of mRNA based on high-resolution mass spectrometry, the purity of mRNA based on CGE-LIF, and the characterization of polymer based on SEC-UV/MALS.

mRNA Specification	Test Item	Method
Content	RNA Concentration	UV
Integrity	mRNA Integrity	CGE
Purity	5’ capping rate	LC-qTOF
	3’ tailing rate	LC-MS/MS
	Product related impurity-polymer	SEC
	Product related impurity-fragment	RP-HPLC
	Process related impurity-Template RNA residue	Quantitative PCR/MS
Others	Appearance	USP<790>
	Solvent residue	USP<467>
	Osmotic Pressure	USP<785>

LNP-mRNA Specification	Test Item	Method
Discrimination	Isoelectric points	CIEF
	Liposome confirmation	RP-HPLC-CAD
Content	RNA content/ RNA encapsulation rate	MALS
	Liposome content	RP-HPLC-CAD
Integrity	LNP size and PDI	DLS
	RNA size and integrity	CGE
Purity	Product related impurity-polymer	SEC
	Product related impurity-fragment	RP-HPLC
Others	Appearance	USP<790>
	Solvent residue	USP<467>
	Osmotic Pressure	USP<785>
	Insoluble particle	USP<787>
	pH	USP<791>

LNP Product Catalogue

Product Code	Product Name	Product Structure	DMF Information
PEG Lipids			
M-DMG-2000	Methoxy PEG Dimyristoyl-rac-glycero, MW 2000		CDER (037950)
			CBER(029458)
			China CDE (F20210000376)
ALC-0159*	Methoxy PEG Ditetradecylacetamide (MW 2000), Or M-DTDAM-2000		CDER(038522)
			CBER(029757)
			China CDE(F20210000577)
DSPE-PEG2000-MAL	DSPE PEG Maleimide, MW 2000		DMFs can be filed at customers’request
HO-PEG2000-DMG	Hydroxyl PEG Dimyristoyl-rac-glycero, MW 2000		China CDE(F20250000021)
DSPECL-PEG2000-SC	DSPE Carbamate PEG Succinimidyl Carbonate, MW 2000		DMFs can be filed at customers’request
DSPECL-PEG2000-AZIDE	DSPE Carbamate PEG Azide, MW 2000		DMFs can be filed at customers’request
DSPECL-PEG2000-PROPARGYL	DSPE Carbamate PEG Propargyl, MW2000		DMFs can be filed at customers’request
Ionizable Lipids			
ALC-0315*	[[4-(4-hydroxybutyl)azanediyl]bis(hexane-6,1-diyl) bis(2-hexyldecanoate), Cas No: 2036272-55-4		CDER(038435)
			CBER(029647)
			China CDE(F20210000466)
SM-102*	heptadecan-9-yl8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy)hexyl)amino)octanoate, Cas No:2089251-47-6		CDER(039154)
			CBER(030165)
			China CDE(F20220000268)
JK-0315-CA	bis(2-hexyldecyl) (((4-hydroxybutyl)azanediyl) bis(hexane-6,1-diyl)) bis(carbonate)		DMFs can be filed at customers’request
JK-102-CA*	heptadecan-9-yl (7-((2-hydroxyethyl) (5-(((undecyloxy)carbonyl)oxy)pentyl)amino) heptyl) carbonate		DMFs can be filed at customers’request
JK-0039	6-((3-(1H-imidazol-1-yl)propyl)(3-(((3S,8S,9S,10R,13R,14S,17R)-10,13-dimethyl-17-((R)-6-methylheptan-2-yl)-2,3,4,7,8,9,10,11,12,13,14,15,16,17-tetradecahydro-1H-cyclopenta[a]phenanthren-3-yl)oxy)-3-oxopropyl)amino)hexyl 2-hexyldecanoate		DMFs can be filed at customers’request
DODAP	1,2-Dioleoyl-3-dimethylammonium-propane		DMFs can be filed at customers’request
Lipid 5(JK-0005)*	heptadecan-9-yl8-((2-hydroxyethyl) (8-(nonyloxy)-8-oxooctyl)amino)octanoate		China CDE(F20260000354)
Cationic Lipids			
DOTAP	1,2-Dioleoyl-3-trimethylammonium-propane, Chloride Salt		Filing in Progress
Phospholipids (Helper Lipids)			
DSPC	17 DSPC (R)-2,3bis(stearoyloxy)propyl (2-(trimethylammonio)ethyl) phosphate		CDER(041639)
			CBER(031534)
			China CDE(F20230000331)

Should the desired structures not be listed in our catalogue, please do not hesitate to make an inquiry. JenKem Technology is prepared to offer custom synthesis for custom LNP Excipients to provide comprehensive support for your R&D and commercial initiatives. Products marked with * may require a license or authorization in certain jurisdictions. Please contact our Sales team for details.